NONIN®

INSTRUCTION AND SERVICE MANUAL

Onyx®

FINGER PULSE OXIMETER

English
Français
Deutsch
Italiano
Español

Declaration of Conformity

Manufacturer:	Nonin Medical, Inc.
Address:	2605 Fernbrook Lane North Plymouth, Minnesota 55447-4755 USA
Model Numbers:	9500

We herewith declare that the above mentioned product is classified as Class IIb and complies with EC Directive No. 93/42/EEC concerning medical devices.

This declaration is based on:

Certification of a Quality System to ISO 9001 : 1994 / EN 46001 : 1996
Certificate Number: Q1 98 09 24497 005
Issued by: TUV Product Service GmbH
Date: December 1998

Certification according to Annex II, Clause 3 of EC Directive No. 93/42/EEC concerning medical devices.
Certificate Number: G1 98 12 24497 004
Issued by: TUV Product Service GmbH
Date: December 1998

Place:	Nonin Medical, Inc. Plymouth Minnesota
Date:	02 December 1998
Signature:	
Name:	Jerry Zweigbaum
Title:	CEO

Authorized EC Representative:
MPS, Medical Product Service GmbH
Borngasse 20
D-35619 Braunfels, Germany

ABOUT THE MANUAL

Shaded boxes draw attention to contraindications, warnings, cautions and notes.

The boxed messages are important. Be sure to read them.

TRADEMARKS

ONYX® is a registered trademark of NONIN MEDICAL, INC.
NONIN. is a registered trademark of
NONIN MEDICAL, INC.

The information in this manual has been carefully checked and is believed to be accurate. In the interest of continued product development, NONIN MEDICAL, INC. reserves the right to make changes and improvements in this manual and the products it describes at any time, without notice or obligation.

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GLOSSARY OF SYMBOLS

SYMBOL	DEFINITION OF SYMBOL
	Attention, Consult ACCOMPANYING DOCUMENTS
	Type BF Equipment: Type B Equipment with an F-Type APPLIED PART (Patient Isolation from electrical shock).
	CANADIAN STANDARDS ASSOCIATION
NRTL/C	Meets both Canadian and United States Standards.
CE 0123	CE Marking indicating conformance to EC directive No. 93/42//EEC concerning medical devices.

CONTRAINDICATIONS, WARNINGS, AND CAUTIONS

CONTRAINDICATIONS:

Do not use the *ONYX* in an MRI environment.

Do not operate the *ONYX* in an explosive atmosphere.

Do not use the *ONYX* on infant or neonatal patients.

WARNINGS:

Batteries may leak or explode if used or disposed of improperly.

CAUTIONS:

Federal Law (USA) restricts this device to sale by or on the order of a physician.

Read this entire manual carefully before using the Nonin *ONYX Oximeter*.

The *ONYX* determines the percentage of arterial oxygen saturation of functional hemoglobin. Significant levels of dysfunctional hemoglobin such as carboxyhemoglobin or methemoglobin may affect the accuracy of the measurement.

Cardiogreen and other intravascular dyes, depending on the concentration, may affect SpO_2 accuracy.

The *ONYX* must be able to measure the pulse properly to obtain accurate SpO_2 measurement. Verify that nothing is hindering the pulse measurement before relying on the SpO_2 measurement. Some situations that may contribute to erroneous pulse measurement are:

- **inadequate perfusion,**
- **excessive patient movement,**
- **oximeter and blood pressure measurement on the same limb, etc.**

CAUTIONS: (CONTINUED)

The *ONYX* may interpret motion artifact of sufficient amplitude and regularity as good perfusion (green).

Do not use the *ONYX* in situations where alarms are required. The *ONYX* has no audible alarms.

The *ONYX* is intended for spot checking or continuous monitoring by an attending health care professional. Because the *ONYX* has no audible alarms, international labeling requirements (ISO 9919) dictate it be labeled, "Not for continuous monitoring".

Check application site periodically (at least every thirty minutes) to determine circulation, positioning and skin sensitivity.

The *ONYX* may not work for all patients. If you are unable to achieve stable readings, discontinue use.

Finger nail polish may reduce light transmission and thereby affect SpO_2 accuracy.

A flexible circuit connects the two halves of the *ONYX*. Do not twist or pull on the connection.

Do not use different types of batteries at the same time. Do not mix fully charged and partially charged cells at the same time. These actions may cause the batteries to leak.

Batteries must be removed if the *ONYX* is going to be stored for more than one month or batteries may leak.

Do not immerse the *ONYX* in liquid to clean.

INTRODUCTION

DESCRIPTION

NONIN MEDICAL, INC has integrated the finger clip sensor and the electronics of the Nonin Model 8500 Hand held Oximeter into one unit, the *ONYX*. The *ONYX* is very small (1.3" w. x 1.3" h. x 2.2" l.) and light weight (two oz.).

The *ONYX* displays numerical values for functional arterial hemoglobin oxygen saturation (**%SpO_2**) in percentage and pulse rate (♡) in beats per minute on light emitting diode (LED) digital displays.

With each detected pulse, the **PERFUSION ❍ DISPLAY** blinks. Patient perfusion signals are graded as good, marginal or inadequate and are indicated as such by the perfusion indicator changing color from green to yellow or red respectively. This sophisticated, yet simple technique provides a pulse-by-pulse visual indication of wave form signal quality, without requiring the user to perform complex signal analysis during critical patient care situations.

Two AAA battery cells power the *ONYX* and operate it for approximately 1,000 spot checks[1] or twelve hours of continuous operation between battery replacement. When the batteries are low, the digital displays will blink once per second. (Refer to Page 9 for battery specifications and Page 10 for battery replacement instructions.)

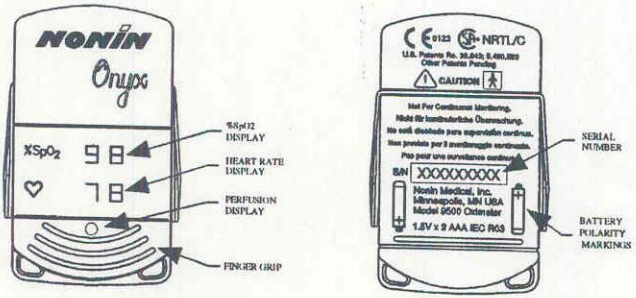


Figure 1. Top Digital Display Illustration and Bottom Label

- **%SpO_2 DISPLAY**
  Numeric LEDs display the value of percent oxygen saturation, calculated using a four beat exponential averaging technique. (Refer to Page 17, *Theory of Operation,* for information on averaging.)

- **HEART RATE ♡ DISPLAY**
  Numeric LEDs display the pulse rate in beats per minute, calculated by an eight beat sliding averaging technique. (Refer to Page 19 for information on averaging.)

- **PERFUSION ○ DISPLAY**
  Provides a visual indication of the signal quality, while blinking at the corresponding pulse rate. It is a method of alerting the user to changes in the pulse wave form signal that may affect the SpO_2 data.

  Green = *good signal amplitude*
  Yellow = *artifact or marginal signal amplitude*
  Red = *inadequate signal amplitude*

CAUTION:
The *ONYX* may interpret motion artifact of sufficient amplitude and regularity as good perfusion (green).

- **BATTERY LOW**
  Numeric LEDs flash once per second when batteries are low. Replace the batteries as soon as possible. Refer to Page 10, *Inserting New Batteries.*

- **FINGER REMOVAL**
  A minus (-) sign appears in the left most digit of the **%SpO_2** display when the *ONYX* senses that the finger has been removed. The last measured SpO_2 and pulse rate values freeze for ten seconds, then the displays go blank.

- The label on the bottom of the *ONYX* lists the model number, serial number, CAUTION statement and battery polarity indicators.

INTENDED USE.

The *ONYX* is a portable device for spot checking or attended-care monitoring of adult or pediatric patients. Use the *ONYX* with finger thickness between 0.3 to 1.0 inches. The *ONYX* is not recommended where motion is expected or for relatively long term monitoring, e.g., greater than thirty minutes.

CONTRAINDICATION:
Do not use the *ONYX* on infant or neonatal patients.

CAUTION:
Do not use the *ONYX* in situations where alarms are required. The *ONYX* has no audible alarms.

CAUTION:
It is intended for spot checking or continuous monitoring by an attending health care professional. Because the *ONYX* has no audible alarms, international labeling requirements (ISO 9919) dictate it be labeled, "Not for continuous monitoring".

CAUTION:
Check application site periodically (at least every thirty minutes) to determine circulation, positioning and skin sensitivity.

CAUTION:
The *ONYX* may not work for all patients. If unable to achieve stable readings, discontinue use.

OPERATING INSTRUCTIONS

GETTING STARTED.

1. **Read this entire manual.**

2. Thread lanyard through lanyard holes on *ONYX* following instructions on Page 8, *Lanyard and Lanyard Lock.*

3. Insert batteries following instructions on Page 10, *Inserting New Batteries.*

4. Activate *ONYX* by inserting finger.

5. Verify operation following instructions on Page 12, *Verifying Operation.*

LANYARD AND LANYARD LOCK.

A lanyard is provided for the convenience of wearing the *ONYX* around the neck or wrist. The *ONYX* will function with or without the lanyard.

1. Thread the ends of the lanyard through the lanyard holes as shown below in Figure 2.

2. Push in the lanyard lock button, slide the lock onto the lanyard up to the desired length.

3. Releasing the lock button to secure its position.

4. Reverse this procedure to remove the lanyard.

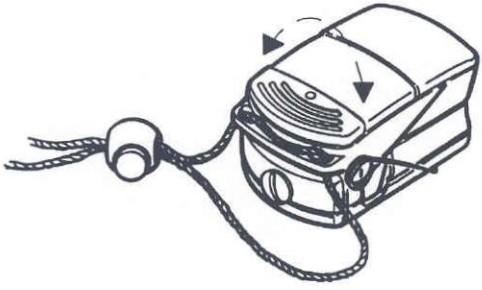


Figure 2. Lanyard and Lock

NOTE:
Lanyard must cross over the top of the *ONYX* to permit full opening of the sensor.

BATTERY REQUIREMENTS.

Nonin Medical, Inc. recommends using AAA alkaline batteries to power the *ONYX*. Two of these batteries are included with each new system.

Concerning the Use of Rechargeable Batteries:

Rechargeable nickel cadmium or nickel-metal hydride batteries may be used. However, rechargeable batteries need more frequent replacement as they have less capacity than non-rechargeable alkaline batteries.

WARNING:
Batteries may leak, or explode if used or disposed of improperly.

CAUTION:
Do not use different types of batteries at the same time or mix fully charged and partially charged cells at the same time as the batteries may leak.

CAUTION:
Batteries must be removed if the *ONYX* is going to be stored for more than one month or batteries may leak.

INSERTING NEW BATTERIES.

1. Loosen the screw at the end of the *ONYX* using a coin or a standard flat screw driver and remove the battery door.

2. Remove the old batteries and dispose of them properly.

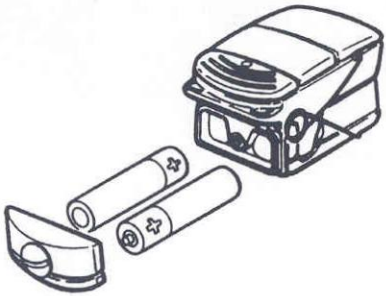


Figure 3. Inserting New Batteries.

3. Insert two new AAA batteries following the polarity markings indicated on the battery door or bottom label of the *ONYX*. **Proper positioning of the batteries is critical.**

4. Carefully position the battery door and firmly, but gently tighten the screw. **Do not force the door in place.** The door only fits when properly oriented. To avoid stripping screw threads, do not tighten excessively.

5. Insert your finger into the *ONYX* and verify operation. If the unit does not turn on, remove finger and wait two seconds before reinserting finger.

6. If the *ONYX* still does not work, reinstall batteries.

ACTIVATING THE *ONYX*.

Activate the *ONYX* by inserting the patient's finger into the oximeter as shown in Figure 4. (The *ONYX* determines that a finger has been inserted and then automatically activates the display.)

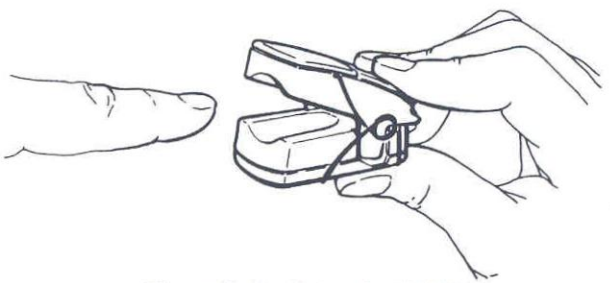


Figure 4. Applying the *ONYX*

1. Insert the patient's finger in the *ONYX* as shown above, until the fingertip touches the built-in stop guide.
2. Center the finger.
3. Verify operation. Turn to Page 12, *Verifying Operation.*

NOTE:
The *ONYX* performs best when used on fingers other than the thumb.

NOTE:
If *ONYX* does not turn on, remove finger and wait two seconds before reinserting finger.

VERIFYING OPERATION.

1. When a finger is first inserted, the *ONYX* executes an initialization sequence.

2. After completing this sequence, the *ONYX* begins sensing the pulse (indicated by the blinking **Perfusion** ○ display).

3. Allow the system to stabilize by observing at least ten seconds of continuous green-colored **Perfusion** ○ pulses (consistent with the patient's pulse) before relying on the displayed values.

4. If the **Perfusion** ○ Display blinks yellow or red, make sure perfusion is not restricted. Try another finger.

5. If you are unable to achieve consistent green perfusion pulses and stable readings, remove the *ONYX* from the patient's finger and refer to Page 23, *Troubleshooting Guide*.

CAUTION:
The *ONYX* may interpret motion artifact of sufficient amplitude and regularity as good perfusion (green).

CAUTION:
Finger nail polish may reduce light transmission and thereby affect SpO_2 values.

NOTE:
If the pulse signal is inadequate for a two minute period the *ONYX* will automatically power down.

CONDITIONS THAT AFFECT USE.

- **Environmental**

  Fluctuating or flickering light may affect measurements.

  Use of the *ONYX* outside stated temperature and humidity specifications may affect measurements., refer to Page 1, *Contraindications, Warnings and Cautions.*

- **Motion**

  Excessive or rapid movement may affect measurements.

- **Sensor Position**

  Sensor position is critical for accurate SpO_2 measurements. All emitted sensor light must pass through the finger before reaching the detector. **Do not allow positioning such that some or all of the emitted light can by-pass the finger as this will result in inaccurate SpO_2 values.**

  While on the finger, do not press the *ONYX* against any surface and do not squeeze or hold the *ONYX*. The external spring provides the correct pressure on the finger; additional pressure may affect measurements.

- **Perfusion**

  The finger must have perfusion adequate to cause the **Perfusion Indicator** ○ to blink green in order to give accurate readings.

- **Nail Polish**

  Fingernail polish may reduce light transmission which may affect SpO_2 values.

In addition, the following factors can degrade performance:

Possible interference from:

- arterial catheter
- blood pressure cuff
- electrosurgical procedure
- infusion line
- cardiovascular dyes
- moisture in *ONYX*
- finger outside 0.3-1.0" size range
- venous pulsations
- anemia or low hemoglobin
- *ONYX* not at heart level

MAINTENANCE

MAINTENANCE.

The solid-state circuitry within the Nonin *ONYX* requires no calibration or periodic maintenance other than battery replacement. Field repair of the *ONYX* circuitry is **not possible.** **DO NOT** attempt to open the *ONYX* case or repair electronics. Opening the case will damage the *ONYX* and void the warranty. If the *ONYX* is not functioning properly, refer to Page 23, *Troubleshooting Guide*.

CAUTION:
A flexible circuit connects the two halves. Do not twist or pull on the flex circuit.

CAUTION:
Do not immerse *ONYX* in liquid to clean.

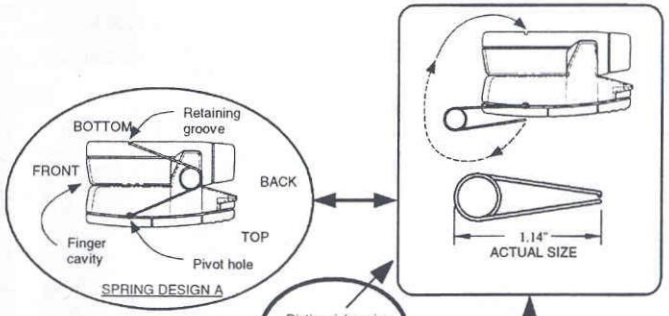
NOTE:
The *ONYX* may be sterilized using ethylene oxide (EtO) (cold cycle). Remove battery door and batteries before EtO sterilization. Follow instructions in Page 10, *Inserting New Batteries*.

NOTE:
Hold the *ONYX* top and bottom together when the spring is released. The two halves are held together by the flex circuit only.

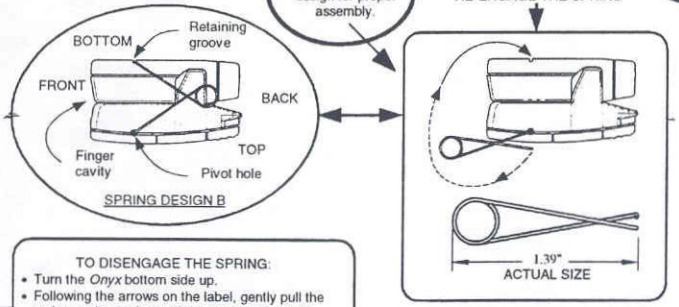
STORAGE REQUIREMENTS.

Store the *ONYX* within stated temperature and humidity storage specifications., refer to Page 20, *Specifications.*

CAUTION:
Batteries must be removed if the *ONYX* is going to be stored for more than one month or batteries may leak.



Distinguish spring design for proper assembly.

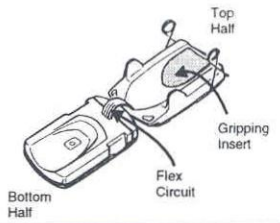


RE-ENGAGE THE SPRING

TO DISENGAGE THE SPRING:
- Turn the *Onyx* bottom side up.
- Following the arrows on the label, gently pull the spring up (to get it out of the retaining groove) and then swing it forward, bringing the spring past the finger cavity.

- To clean the inner surfaces.
- To replace the spring.
- To replace the gripping insert.

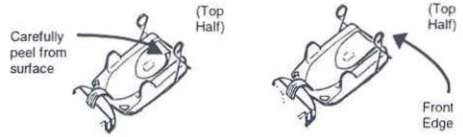
TO CLEAN THE INNER SURFACES:
- Wipe exposed surfaces with a soft cloth dampened with an isopropyl alcohol solution or a mild detergent solution.
- Dry with a soft cloth or allow to air dry.
- Surfaces should be thoroughly dry before re-engaging the spring.



TO REPLACE THE SPRING:
- Remove the old spring, carefully pulling the ends from the pivot holes on either side.
- Insert the ends of the new spring into the pivot holes and swing the spring up and past the finger cavity, then seat the spring into the retaining groove.

TO REPLACE THE GRIPPING INSERT:

A gripping insert adhered to the upper interior surface of the *Onyx* provides a more secure fit to the finger. The *Onyx* will function with or without the gripping insert, however Nonin recommends that the insert be in place during normal operation.



- Carefully peel the old gripping insert away from the surface.
- Remove any residual adhesive with an isopropyl alchohol solution.
- Peel the backing paper off the new gripping insert, uncovering the adhesive back.
- Position the new insert as shown above and gently press it in place.

MAINTENANCE CHOICES.

Cleaning and replacing the spring and the gripping insert.

THEORY OF OPERATION

OXIMETRY.

The pulse oximeter shines red and infrared light through the tissue and detects the fluctuating signals caused by arterial blood pulses. The ratio of the fluctuation of the red and infrared light signals received determines the oxygen saturation content. Conditions such as steady venous blood flow, skin thickness, finger nail thickness, etc., do not affect the saturation reading because they are constant and do not cause fluctuations.

The function, *f*, does depend on the physical properties of the LEDs producing the light. These physical properties are fixed by the manufacturing material and processes.

$$SpO_2 = f\left[\frac{\ln\left(\frac{min}{max}\right)_{Red}}{\ln\left(\frac{min}{max}\right)_{IR}}\right]$$

Note that the oximeter's readings do not depend upon the absolute light intensity, rather upon the fluctuations in light intensity. Characteristics such as thick skin or skin pigmentation will affect the **min** and **max** proportionally, thus the ratio **min/max** does not change. However, if too little light passes through, the oximeter will not display values. Pulse oximeters use two different wavelengths of light (red and infrared), providing the ability to determine one component of blood. The oximeter is calibrated to closely approximate functional oxygen saturation values. These values will closely approximate laboratory instrument functional saturation values if the dysfunctional hemoglobin saturation levels are negligible.

In summary, because the oximeter performs all computations from the internal software and there are no critical parts to drift, no re-calibration is needed.

If the dysfunctional hemoglobin is carboxyhemoglobin or methemoglobin, the difference between the oxygen saturation value displayed by the oximeter and the oxygen saturation values determined by the laboratory instrument will be greater as the dysfunctional hemoglobin levels rise approximately in accordance with the following formulas:

$$SpO_2 = O_2Hb + COHb + MetHb$$

$$SaO_2 = 100\left(\frac{O_2Hb}{100 - COHb - MetHb}\right)$$

Where:

SpO_2 = *ONYX* determined and numerically displayed oxygen saturation in percent

O_2Hb = Fractional oxyhemoglobin saturation in percent

COHb = Carboxyhemoglobin saturation in percent

MetHb = Methemoglobin saturation in percent

SaO_2 = Functional oxygen saturation in percent

Example 1	**Example 2**
O_2Hb = 96	O_2Hb = 88
COHb = 0.5	COHb = 8
MetHb = 0.6	MetHb = 2
SpO_2 = 97	SpO_2 = 98
SaO_2 = 97.07	SaO_2 = 97.78

ONYX AVERAGING.

For pulse rates below 112 BPM the averaging calculation is based on a four beat exponential average for SpO_2 (see below) and an eight beat sliding average for pulse rate. For pulse rates above 112 BPM the averaging is doubled and then re-doubled above 225 BPM. The oximeter will not include questionable pulses in the average. Marginal pulses may count less in the average than good pulses.

All averages are updated on a beat-by-beat basis. The display is updated every one and one-half seconds with the most recent value.

Also if the oximeter signal is "noisy" or missing, the display will hold the last value for ten seconds before showing dashes. With the four beat exponential average, the effect of each measurement gradually decreases beat by beat. Each measurement initially counts for one fourth of the average. This weight is decreased by multiplying three fourths on each succeeding beat:

Beat	Effect (weighting in average)
1	¼ = 0.250
2	x ¾ = 0.1875
3	x ¾ = 0.1406
4	x ¾ = 0.1055
5	x ¾ = 0.0791

The SpO_2 four beat exponential average is fast enough to follow physiological changes.

For the pulse rate sliding eight beat average, each beat counts one eighth for eight beats and thereafter has no affect on the average.

SPECIFICATIONS

1. Oxygen Saturation Range	0 to 100%
2. Pulse Rate Range	18 to 300 pulses per minute
3. Displays	
a) Patient Indicators	Tri-color perfusion light emitting diode (LED)
b) Digital Displays	Two 3-digit 7-Segment LEDs
4. Measurement Wavelengths	
a) Red:	660 Nanometers
b) Infrared:	910 Nanometers
5. Accuracy	
a) $\%SpO_2$ Accuracy ($\pm$ 1 S.D.)[2]	70-100% $\pm$ 2 digits
b) Rate Accuracy	$\pm$ 3% $\pm$ 1 digit
6. Temperature	
a) Operating	32°F to 122°F (0° to +50°C)
b) Storage/ Transportation	-4°F to 122°F (-20° to +50°C)
7. Humidity	
a) Operating	10 to 90% Non Condensing
b) Storage/ Transportation	10 to 95% Non Condensing
8. Power Requirements	Two AAA Cells
9. Battery Life	
a) Operating	Approximately twelve hours of continuous operation[3]
b) Storage	Three months[2]
10. Patient Isolation	Not Applicable
11. Leakage Current	Not Applicable
12. Dimensions	1.3" W x 1.3" H x 2.2" L (3.3 Cm x 3.3 Cm x 5.7 Cm)
13. Weight	Two ounces (60 gm), including two AAA alkaline batteries

[2] Standard Deviation (S.D.): Up to 32% of the readings may fall outside these limits.

[3] Using 2 AAA alkaline batteries.

PARTS AND ACCESSORIES

PARTS.

PART NUMBER	DESCRIPTION
1956-000	9500 BATTERY DOOR and CONTACT
1817-000	GRIPPING INSERT
1650-000	9500 EXTERNAL SPRING
1966-000	LANYARD CORD and LOCK (Black)
2031-001	LANYARD CORD and LOCK (Yellow)

ACCESSORIES.

The following accessories function with the Nonin *ONYX*:

Model 9440 Finger Phantom (oximeter testing device)

For information regarding parts and accessories, contact your local sales representative or distributor.

For the sales representative or distributor in your area contact NONIN at (800) 447-*ONYX*.

TECHNICAL SUPPORT.

For technical support and before returning any equipment, call NONIN:

(800) 356-8874 (toll free inside the U.S. and Canada)
(612) 553-9968 (local and international)
(612) 553-7807 (FAX)

WARRANTY

NONIN MEDICAL, INC. (NONIN) warrants to the purchaser that the *ONYX* (excluding batteries, lanyard and lanyard lock) will be free from defects in material and/or workmanship for one year from the date of delivery. During the warranty period, NONIN will correct any defects in material or workmanship to conform to specifications, free of charge. NONIN reserves the right to replace the *ONYX* with a comparable unit. Shipping costs are the responsibility of the purchaser. Any replacement parts or units are warranted for the remainder of the original warranty period. The purchaser must notify NONIN of a defect within the applicable warranty period, and return the *ONYX* in question. Proof of purchase may be required before any warranty consideration by Nonin occurs. This warranty is not transferable.

Any sign of tampering with the *ONYX*, voids the warranty in its entirety.

This warranty shall be the sole and exclusive remedy by the purchaser thereunder for any units or accessories delivered to the purchaser that are found to be defective in any manner, whether such remedies be in contract, tort or by law.

DISCLAIMER AND EXCLUSIVITY OF WARRANTY:

THE EXPRESS WARRANTIES SET FORTH IN THIS MANUAL ARE EXCLUSIVE AND NO OTHER WARRANTIES OF ANY KIND, WHETHER STATUTORY, WRITTEN, ORAL, OR IMPLIED INCLUDING WARRANTIES OF FITNESS FOR A PARTICULAR PURPOSE OR MERCHANTABILITY SHALL APPLY.

The purchaser agrees to pay a $100.00 service charge for a warranty repair request on any *ONYX* sent to NONIN that is determined to be within specification.

Non-warranty work is charged at the minimum repair rate effective at the time of the *ONYX* return to NONIN. All repairs include a complete functional test using factory test fixtures.

TROUBLESHOOTING GUIDE

SYMPTOMS	POSSIBLE CAUSE	POSSIBLE SOLUTION
Numeric displays blinking at one second intervals.	Batteries are low.	Replace batteries immediately. See Page 9 and 10.
ONYX will not activate.	Batteries incorrectly inserted.	Check batteries. See Page 9 and 10.
	Depleted batteries.	Replace batteries. See Page 10.
	ONYX not attached to patient	Apply *ONYX* to patient. See Page 11.
	ONYX turned off while on finger.	Remove *ONYX* from finger, then reinsert finger.
Minus (-) sign in left most digit of the %SpO_2 display.	Poor signal.	Reposition finger.
	Finger removal.	Reinsert finger.
	ONYX not functioning.	Call NONIN Technical Service Department, (800) 356-8874.
Unable to obtain green perfusion.	Low patient pulse strength.	Reposition *ONYX* on finger.
	Finger poorly perfused.	Reposition *ONYX* on finger.
	Finger not correctly positioned.	Reposition *ONYX* on finger.
	Possible interference from: • arterial catheter • blood pressure cuff • electrosurgical procedure • infusion line	Reduce or eliminate interference.
	Circulation reduced because of excess pressure between *ONYX* and hard surface after inserting finger.	Allow *ONYX* and finger to rest comfortably on surface.
	Excessive ambient light.	Reduce ambient light.
	Excessive patient motion.	Reduce patient motion.
	ONYX applied to polished fingernail.	Remove fingernail polish.

For further information contact:

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